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10/696,178	10/29/2003	Katerina Leftheris	QA0237 Div 1	6531
23914 7590 07/02/2008 LOUIS J. WILLE BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000				
EXAMINER FRYOR, ALTON NATHANIEL				
ART UNIT		PAPER NUMBER		
1616				
NOTIFICATION DATE		DELIVERY MODE		
07/02/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@BMS.COM
patents@bms.com
eileen.immordino@bms.com

Office Action Summary

Application No.

10/696,178

Applicant(s)

LEFTHERIS ET AL.

Examiner

ALTON N. PRYOR

Art Unit

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/CI/CD)
- Paper No(s)/Mail Date 2/8/08

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Detailed Action

Applicant's arguments filed 4/9/08 have been fully considered but they are not persuasive. See discussion below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,2,5,6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt on record. Hunt teaches the pyrrolotriazine where Y is absent; R1 = H; X = -NR11C=O-; R2,R3 = H,Me; ZR5 = NH; R4 = carbmyl-alkoxy substituted phenyl; R13 = alkyl and R11 = H or alkyl. See abstract, column 1 lines 21-36, column 2 line 52 - column 2 line 40, column 4 lines 17 - 33, claim 1. Hunt's pyrrolotriazine compound is equivalent to instant compound where R1 = H; R2, R3 = H, methyl; X = -NR10C=O-; R10 = H or alkyl; ZR5 = NH; and R4 = carbmyl-alkoxy substituted phenyl. Hunt teaches that pyrrolotriazine compounds of his invention can be used in methods of treating cancer, psoriasis, arthritis, inflammation, autoimmune disease, and diabetic retinopathy. See column 6 line - column 7 line 10. These are conditions associated with p38 kinase activity as indicated in instant claims 7-8. Hunt does not exemplify methods of treating said conditions with his compound described above. However, it would have been obvious to one having ordinary skill in the art to have employed the compound described in methods of treating said conditions. One would have been motivated to do

this since Hunt states that his invention is based on the discovery that certain pyrrolotriazines are inhibitors of protein kinases. See column 6 lines 44-45.

Response to Applicant's arguments

Applicants argue:

1) Hunt does not exemplify compounds with current definition of $-Z(R4)(R5)$ and especially does not describe the ortho methyl group as claimed. Hunt defines the values of R4 and R5 as being selected from the same substituents.

2) Hunt's compounds target tyrosine kinase not p38 kinase. Tests for at least 5 compounds from the present invention, i.e. compounds in Examples 70,97,111,114 and 119 show good activity for p38. Example 70 in the present invention was tested but showed no meaningful activity against tyrosine kinases as described in Hunt.

Examiner argues:

1) Hunt suggests the instant $-Z(R4)(R5)$ structural definition. Hunt teaches that $ZR5 = NH$, $R4 =$ carbmyl-alkoxy substituted phenyl (column 3 line 10, column 3 lines 23-24, column 4 lines 23-33). This teaching in Hunt makes obvious the instant definition of $-Z(R4)(R5)$. Note it is not necessary for a reference to exemplify a compound in order to make the compound obvious.

2) None the compounds (Examples 70,97,111,114 and 119) tested for p38 kinase activity possessed the claimed structural definition for $-ZR4R5$.

For the above reasons the rejection over Hunt is maintained.

New Rejections

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,2,5 and 6 recites the limitation "R26" and "R27" in the definition of R2.

There is insufficient antecedent basis for this limitation in the claim.

Claims 1,2,5 and 6 recites the limitation "R20" on page 4 of claim 1, "R12" on page 5 of claim 1 and "R13" page 6 of claim 1 and "R2c" on page 7 in claim 6. There is insufficient antecedent basis for these limitation in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,2,5,6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18,24 of U.S. Patent No. USPN 6670357. Although the conflicting claims are not identical, they are not patentably distinct from each other because USPN '357 makes claim to compound of formula II

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where R3 = CH3, CF3; R23 = alkoxy; Y = -CONR23; R18 = alkoxy; X = -carbonyl, absent; R2 = H, alkyl; R6 = hydrogen and R13 = CH3 (i.e., instant compound in method claim where X = -carbonyl; R1,R2,R6 = H or alkyl; R3 = CH3; ZR4 =NH; R5 = carbmyl-alkoxy substituted phenyl). Claim 24 in USPN '357 suggests that the compounds in claim 1 can be administered to a patient for treating numerous conditions such as arthritis. USPN '357 does not specifically recite such a claim, but the USPN suggests such treatment claim. This suggestion by the USPN claims makes the instant method claims of treating patients suffering from arthritis with instant compounds enclosed/described therein obvious.

Claims 1,2,5,6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. USPN 7314876. Although the conflicting claims are not identical, they are not patentably distinct from each other because USPN '876 makes claim to compound of formula Ib where R3 =CH3; X= N or CH; n = 0; R1 and R4 = H; R6a = CH3; R6b = H; R6c = -CONH-m -CONHCH3, -CO- and NHR7 (i.e., instant compound in method claim where R1 R3,R4,R6 = H; ZR4 = NH; R5 = carbmyl-alkoxy substituted phenyl; X = -carbonyl; R2 = aryl or pyridine). Claim 3 in USPN '876 suggests that the compounds in claim 1 can be administered to a patient for treating numerous conditions such as arthritis. The USPN suggests such treatment claim. This suggestion by the USPN claims makes the instant method claims of treating patients suffering from arthritis with instant compounds enclosed/described therein obvious.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alton N. Pryor/
Primary Examiner, Art Unit 1616